| Office Action Summary | Application No. 09/973,256 | Applicant(s) KIS ET AL. | |
|---|---|---|---|
| | Examiner Frederick C. Nicolas | Art Unit 3754 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *31 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *25-33* is/are pending in the application.

4a) Of the above claim(s) *1-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 25 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebert et al. 5,256,154 in view of Czaplinski et al. 3,709,365.

Liebert et al. discloses a pharmaceutical package as best seen in figure 1, which comprises a polypropylene bottle (20) in which is disposed a solution (12), the solution comprises a pharmaceutical product (column 1, lines 8-16), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (column 3, lines 40-45), autoclaving the package (column 5, lines 15-36), after the autoclaving of the package, the package suffers no deformation, does not shrink and does not explode, and where the package retains a sufficiently high squeezability to dispense the solution as best seen in Figure 1, a plastic nozzle tip (24) for dispensing the solution. Liebert et al. lacks after autoclaving at at least 121°C and for at least 20 minutes. Czaplinski et al. teaches the use of autoclaving a polypropylene at about 115°-125°C. from 20-30 minutes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Czaplinski et al. into the package of Liebert et al. as such, in order to treat a material that can withstand autoclaving at a

temperature 121°C for at least 20 minutes, as taught by Czaplinski et al. (column 2, lines 49-53).

As to claim 32, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Liebert et al. as such, in order to comply with the requirements of the European Pharmacopoeia, 3rd edition (1997), as such is notoriously well known in the art.

3. Claims 25-26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf 5,842,326 in view of Weiler et al. 4,178,976 and Czaplinski et al. 3,709,365.

Wolf discloses a pharmaceutical package as best seen in figure 1, which comprises a plastic bottle (5) in which is disposed a solution (2), the solution comprises a pharmaceutical product (column 5, lines 51-54), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (column 6, lines 35-37), autoclaving the package (column 7, lines 4-24), after the autoclaving of the package, the package suffers no deformation, does not shrink and does not explode, and where the package retains a sufficiently high squeezability to dispense the solution as best seen in Figure 1, note: it is inherent that Wolf's package retains a sufficiently high squeezability to dispense the solution in as much as the applicant's claimed invention, a plastic nozzle tip (8) for dispensing the solution, a cap (7) for closing the bottle, where the bottle has walls that have a wall-thickness as best seen in Figure 1 and note: it is

inherent that the Wolf's bottle has walls that have a wall-thickness in as much as the applicant's claimed invention, a bottom portion (17). Wolf lacks after autoclaving at at least 121°C and for at least 20 minutes, and the bottle is made of polypropylene. Weiler et al. teaches the use of a polypropylene bottle (60) (column 4, lines 39-64). Czaplinski et al. teaches the use of autoclaving a polypropylene at about 115°-125°C. from 20-30 minutes (column 2, lines 49-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Weiler et al. into Wolf's bottle as such, in order to provide a package with a material of construction, which is pharmaceutical as well as food products can be readily packaged, as taught by Weiler et al. (column 4, lines 48-52).

It also would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching of Czaplinski et al. into Wolf's package as such, in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes, as taught by Czaplinski et al. (column 2, lines 49-53).

As to claim 32, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wolf's package as such, in order to comply with the requirements of the European Pharmacopoeia, 3rd edition (1997), as such is notoriously well known in the art.

4. Claims 27-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf 5,842,326 in view of Weiler et al. 4,178,976 and Czaplinski et al. 3,709,365 as applied to claim 26 above, and further in view of Carter 5,033,252.

Wolf-Weiler et al.-Czaplinski et al. combination has all the features of the claimed invention except for the bottle comprises a neck portion that includes an externally threaded portion and the cap has internal threads. Carter's shows a polypropylene bottle (20) with a neck portion (26b) that includes an externally threaded portion and an outer rim, which defines an outlet (column 3, lines 24-27) and as best seen in Figure 2, a nozzle tip (40), a cap (22), which has internal threads (26a) for engagement with the externally threaded portion of the neck portion of the bottle as best seen in Figures 1-2.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wolf's bottle neck and nozzle tip with Carter's bottle neck, nozzle tip (40) and cap (22), in order to provide an alternate means of securing the cap onto the bottle neck for providing a product tight seal.

As to claim 27, the claimed subject matter "the bottle is made of Appryl 3020 SM 3, the nozzle tip is made of Appryl 3020 SM 3, and the cap is made of HDPE GC 7260.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the bottle, the nozzle tip and the cap as such, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

As to claim 29, the claimed subject matter "said bottom portion of said bottle has a concave configuration".

At the time the invention was made, It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify Wolf's bottom portion with a concave configuration, because applicant has not disclosed that a concave configuration of the bottom portion provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with Wolf's bottom portion, because Wolf's bottom portion prevents the product from seeping out of the bottle.

Therefore, it would have been an obvious matter of design choice to modify Wolf's bottom portion to obtain the invention specified in claim (29).

As to claim 30, the claimed subject matter, the bottle has a wall-thickness in the range of 0.3 mm to 0.6 mm, as well as the claimed subject matter in claim 31.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wolf's wall-thickness as such, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. As per MPEP 2144.05

As to claim 33, lines 1-3, the claimed subject matter "wherein physical properties of said polypropylene meet requirements laid down in the supplement of 1998 of the European Pharmacopoeia, 3rd edition (1997).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Wolf's package as such, in order to comply with the

requirements of the European Pharmacopoeia, 3rd edition (1997), as such is notoriously well known in the art.

***Response to Arguments***

5. Applicant's arguments filed 12/31/2002 have been fully considered but are moot in view of the new ground(s) of rejection. Any remaining arguments have been fully addressed in the above rejection.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vacca 5,373,684, Hall et al. 5,316,054, Godat et al. 5,472,431,

Vacca 5,380,295 and Jurgens, Jr. et al. 4,718,463 disclose other types of pharmaceutical package.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick C. Nicolas whose telephone number is (703)-305-6385. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mancene L Gene or acting supervisor Ehud Gartenberg, can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9302, and for after final is (703)-872-9303.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0861.

FN
February 23, 2003

F.N 2/24/03

Ehud Gartenberg

EHUD GARTENBERG
PRIMARY EXAMINER